



July 3, 1996

510(k) GTI PAKAUTO Screening Test for Autoantibodies to Platelet Glycoproteins, IIb/IIIa, Ib/IX, and Ia/IIa

This statement regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I certify that Genetic Testing Institute will make available all information included in this premarket notification on safety and effectiveness that supports a finding of substantial equivalence within 30 days of request by any person. The information to be made available will not include confidential patient identifiers or confidential or trade secret manufacturing process information.

Michael Moghaddam
Signature, Michael Moghaddam

7.5.96
Date